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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,481	12/22/1998	NICHOLAS VAN BRUGGEN	11669.41US01	2987

7590

04/09/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

26

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/218,481

Applicant(s)

VAN BRUGGEN ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,8-21 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 3-6,11-21 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1642

### DETAILED ACTION

1. The amendment filed Dec. 18, 2002, is acknowledged. Claim 1 was amended.

Claims 1, 3-6, 8-21, 27-29 are pending.

Claims 2-6, 11-21 and 27-29, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1 and 8-10 are examined on the merits.

2. The declaration filed under 37 CFR 1.132, by Dr. van Bruggen, has been considered.

#### ***Claim Rejections Withdrawn:***

3. The rejection of claims 1 and 8-10 under 35 USC 112, 1<sup>st</sup> paragraph, for lack of enablement of the full scope of the claimed invention is withdrawn in view of the amendment to claim 1.

4. The rejections of claims 1 and 8-10 under 35 U.S.C. 103(a) are withdrawn upon further consideration.

#### ***New Grounds of Rejection:***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1642

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrara et al (WO 94/10202; published 11 May 1994).

Claims 1 and 8-10 are drawn to methods of treatment comprising administering to a mammal a hVEGF antagonist, wherein the hVEGF antagonist comprises an anti-hVEGF antibody. The purpose of the method of treatment is to reduce cerebral edema in a mammal. The anti-hVEGF antibody may consist of murine variable domains and human constant domains, may comprise a humanized antibody, or may comprise a monoclonal antibody.

Ferrara teaches methods of treatment comprising administering hVEGF antagonists, where the hVEGF antagonist may be an anti-hVEGF antibody (see page 22, lines 10-33; claim 28; page 2, line 29 – page 3, line 4; ). Thus, Ferrara teaches methods that are the same as that claimed, because the active step of the claimed methods are the same as the active step of the methods taught by Ferrara. Furthermore, it appears that Ferrara appreciated that hVEGF antibodies would be useful in the treatment of diseases or disorders characterized by undesirable vascular permeability, such as edema (see page 3).

The declaration of Dr. van Bruggen is not sufficient to overcome the new grounds of rejection, because the declaration is concerned with the fact that a human VEGF antagonist would not be useful in a rat model. However, the scope of the claims is not confined to the treatment of rats. Another reason that the declaration is not sufficient to overcome the new grounds of rejection is that if the prior art teaches a method that comprises the same steps of

Art Unit: 1642

administering a pharmaceutical agent as a claimed method, it is not necessary for the prior art to teach a new effect of the same pharmaceutical agent.

***Conclusion***


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
March 24, 2003

  
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